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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/672,519

09/27/2000

Bruce W. Gibbs

BC-0256-P02

2122

24994

7590

10/03/2007

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EXAMINER

BIANCO, PATRICIA

ART UNIT

PAPER NUMBER

3772

MAIL DATE

DELIVERY MODE

10/03/2007

PAPER

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 09/672,519
Filing Date: September 27, 2000
Appellant(s): GIBBS

**MAILED
OCT 03 2007
GROUP 3700**

Laura B. Arciniegas
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/7/2006 appealing from the Office action mailed 7/26/2004.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

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(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The evidence relied upon in this appeal is **Keller et al. U.S. Patent No. 6,200,287** and **Minshall U.S. Patent No. 5,009,654**.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A). Claims 1 and 5-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Keller et al. (U.S. Patent No. 6,200,287). This rejection is reproduced below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5-10 remain rejected under 35 U.S.C. 102(e) as being anticipated by Keller et al. (6,200,287). Keller discloses an apheresis system and method wherein the system includes a disposable preconnected cassette assembly as well as a

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number of tubing assemblies (20/50/60/80/90/100) interconnected thereto. Tubing assembly (20/60) is a blood inlet/return and blood component return assembly. A blood processing vessel (352), i.e. centrifuge, is interconnected to the tubing assemblies and cassette. A red blood cell collection assembly is connected to the cassette for receiving separated red blood cells and comprises a collection bag (950). Keller further teaches that selective filtering may be desired to remove white blood cells. For example, leukoreduction may be desired to reduce any likelihood of febrile non-hemolytic transfusion reactions. If such leukoreduction is deemed appropriate, the red blood cell/storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag (954) through a filter and into a new storage bag. A plasma collection bag (94) and a platelet collection bag (84) are connected to the cassette assembly via tubing. During use, blood is removed from a patient or donor, separated into components, including RBC, platelets, and plasma, using a centrifuge vessel using the pre-connected disposable system and red blood cell collection assembly. The components, including RBC, plasma and platelets, are stored in their respective containers. Keller also teaches that the RBC may pass through a leukocyte filter before being finally stored. Keller also discloses that the RBC collection tubing assembly further includes a sterile barrier filter/drip spike assembly (956). Also, a storage solution may be added that advantageously facilitate storage of the RBCs for a longer period of time than without storage solution. The solution may be contained in a separate storage solution bag that can be selectively interconnected to the RBC collection bag. Such selective

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interconnection may be provided via sterile-docking tubing utilizing a sterile connecting device, such as by the sterile barrier filter/drip spike assembly. The use of assembly facilitates the maintenance of a closed system, thereby effectively avoiding bacterial contamination. Since Keller discloses that the leukocyte filter is used to provide leukoreduction and that the red blood cell/storage solution mixture can be connected to a commercially available red cell filter/bag so that red blood cells are gravity transferred from the collection bag (954) through a filter and into a new storage bag, it is implicit that the system will have a filter connected to a RBC storage reservoir or bag. This filtration is inherently done after centrifugation. Further, since a storage solution would be added to the final RBC storage bag or reservoir, and is taught to be connected to the bag via the barrier/spike and storage solution, it would inherently be placed between the centrifuge and leukoreduction filter to achieve the desired leukocyte free product. See figures 1, 2A & 2B as well as the entire disclosure.

B). Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (U.S. Patent No. 6,200,287). This rejection is reproduced below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 2 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. ('287). Keller et al. discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the air removal bag is interconnected to the RBC storage bag. Keller does disclose the use of an air removal tubing segment (100) including an air removal bag (104) that is connected to the cassette assembly for receiving air from the cassette assembly and the centrifuge during priming. It would have been obvious at the time of the invention to connect the air removal bag to the RBC storage bag to remove air therefrom, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

C). Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. (U.S. Patent No. 6,200,287) in view of Minshall (U.S. Patent No. 5,009,654). This rejection is reproduced below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4 & 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Keller et al. ('287) in view of Minshall et al. (5,009,654). Keller et al. discloses the

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invention substantially as claimed, see rejection supra, however, fails to disclose specifically the use of frangible connectors in the tubing between the leukoreduction filter and RBC collection bag. Keller does teach of selective interconnection being provided via sterile-docking tubing utilizing a sterile connecting device, such as by the sterile barrier filter/drip spike assembly.

Minshall discloses a tubing assembly that is a closed apheresis kit or circuit containing tubing and bags connected. It is also taught that the tubing may include normally closed frangible connectors in the flow path of each portion to keep the circuit sterile. At the time of the invention, it would have been obvious to one having ordinary skill in the art to modify the tubing of Keller to include frangible connectors in the tubing between the filter and collection bag to keep the pathway sterile, since Keller suggests the use of an assembly that is a closed system to effectively avoiding bacterial contamination.

(10) Response to Argument

A). With respect to the rejection of claims 1, 5 and 6, Applicant argues that Keller does not disclose a disposable having a preconnected red blood cell filter (pg. 5, section VIII (A) of appeal brief). None of the claims recite a red blood cell filter; however, claim 1 does recites a leukoreduction filter as part of the disposable. Therefore, the arguments have been treated as being directed to a leukoreduction filter. Applicant further argues that the mere possibility that Keller's teaching that a leukoreduction filter "can be connected" to the disposable does not inherently imply that the filter is preconnected or integrated into the disposable as claimed.

With respect to the recitation that the filter is preconnected between the red blood cell (RBC) collection bag and the RBC storage bag, it is the position of the Examiner that Keller meets this limitation. Keller discloses an embodiment of using the disposable wherein it is desirable to filter out leukocytes from the collected RBC. Keller teaches that the RBC are collected into a collection bag or reservoir, the bag is connected to a commercially available filter to filter out the leukocytes, and the filtered RBC product is then transferred into a new storage bag (see col. 55, lines 20-39). In order to carry out the leukocyte filtration, one would have to connect the filter to the tubing and a storage bag resulting in a preconnected or interconnected leukoreduction filter. Regardless of when the connection of the filter is made, the filter is preconnected between the collection bag and the storage bag.

With respect to the argument that the teaching in Keller that a leukoreduction filter "can be connected" to the disposable does not inherently imply that the filter is preconnected or integrated into the disposable as claimed the Examiner respectfully disagrees. Keller discloses multiple embodiments of the disposable set. Keller states that if it is desired, RBC can be or may be passed through a filter before storage to remove leukocytes. This is a teaching for connecting a leukocyte filter to the disposable. Again, in order to carry out the leukocyte filtration, one would have to connect the filter to the tubing and a storage bag resulting in a preconnected or interconnected leukoreduction filter. Regardless of when the connection of the filter is made, the filter is preconnected between the collection bag and the storage bag.

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B). With respect to the rejection of claim 2, Applicant argues that Keller does teach of an air removal bag interconnected to the red blood cell storage bag and that the prior art does not provide motivation or reason for rearranging the parts of the invention as set forth in the rejection. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Keller teaches that instead of the vent bag assembly being connected to the reservoir of the assembly, other integral passageways, integrated chambers, and tubing loops could be used as part of the assembly to perform the same functions as the vent bag tubing assembly, that of receiving sterile air out of the assembly. Therefore, the motivation to rearrange the connection of an air removal bag to the RBC storage bag is provided.

C). With respect to the rejection of claims 3 and 4, Applicant argues that Minshall does not disclose the use of a frangible connector to enable red blood cells to pass through the tubing between a filter and a RBC collection bag (claim 3) nor does Minshall disclose frangible connectors for the connections between the RBC collection

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bag and a storage solution container (claim 4). Applicant further argues that the tubing of invention is a single distinct piece of tubing which contains the frangible connector.

Minshall discloses a disposable assembly for use in a medical fluid process, such as a closed apheresis circuit (see col. 4, lines 58-63). A processing apparatus has multiple tubing segments, each having end portions that are frangible closures to maintain a sealed, sterile tube (col. 6, lines 25-42). Keller teaches that the tubing of the system may be employed for sterile docking of tubing, that is the direct connection of two pieces of tubing (col. 20, lines 9-11). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to modify the tubing of Keller with frangible connectors as taught by Minshall is to provide a sterile connector for the tubing.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tubing of invention is a single distinct piece of tubing which contains the frangible connector) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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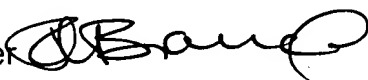
(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Patricia Bianco
Primary Examiner



Conferees:
Angela Sykes
George Evanisko

